

years) who started antipsychotic treatment during July 1, 2001 and December 31, 2003. Antipsychotic users were followed for up to six months using an intent-to-treat approach. Extended Cox proportional hazard regression model stratified on matched pairs based on the propensity score was used to evaluate the comparative risk of death among users of typical and atypical antipsychotic agents. **RESULTS:** There were 84, 162 (42, 081 atypical and 42, 081 typical) users of antipsychotic agents in the final matched cohort. The unadjusted mortality rate was 11.12% (4, 682) for atypical users and 15.01% (6, 318) for typical users. Results of Cox regression suggest that, typical users were more likely to die compared to atypical users [Hazard Ratio (HR) 1.59, 95% Confidence Interval (CI) 1.52-1.66]. The extended Cox model revealed that the risk of death was greater with typical use during the initial 40 days of treatment [<40 days: HR 2.00, 1.86-2.15]. The difference in risk persisted after 40 days of typical antipsychotic use [40-180 days: HR, 1.40, 1.32-1.47]. **CONCLUSIONS:** The use of typical antipsychotic agents was associated with short-term and long-term risks of mortality among elderly dual eligible beneficiaries compared to atypical use. Given the underlying poor health status of dual eligible beneficiaries, the study findings suggest that the use of typical agents needs to be optimized in the vulnerable elderly population.

RM4

A SYSTEMATIC REVIEW OF COSTS ASSOCIATED WITH PRESCRIPTION OPIOID RISKS

Cangelosi MJ, Saunders T, Neumann PJ, Cohen JT
Tufts Medical Center, Boston, MA, USA

OBJECTIVES: The US Food and Drug Administration (FDA) requires drug manufacturers to implement Risk Evaluation and Mitigation Strategies (REMS) to ensure drug benefits outweigh their risks. REMS for opioids target abuse, misuse, addiction, and overdose deaths. This study aims to identify which among these REMS-designated risk categories contribute most to societal burden, where burden is the product of prevalence (or rate for death) and per-event cost. This study also examines opioid diversion risk as a non-REMS secondary outcome. **METHODS:** Based on systematic review and meta-analysis, we estimated opioid-related mortality and prevalence for other outcomes. For outcomes other than death, we estimated health care costs per occurrence as documented by the Healthcare Cost and Utilization Project (HCUP) dataset. We focused on the value people place on avoiding death, rather than on the health care resources consumed. As such, we estimated the cost of each death using the Environmental Protection Agency's value of a statistical life (VSL), which reflects willingness to pay to avoid mortality risks. **RESULTS:** Excluding populations at high-risk for adverse behaviors, prevalence rates were 6% to 38% for misuse, 6% to 15% for abuse, 0.3% to 0.4% for addiction, and 9% to 20% for diversion. Mortality varied widely, ranging from 1 to 108 per 100,000 person years. Treatment costs per occurrence were \$8,300 for abuse, \$7,400 for addiction, and \$10,000 for diversion. Misuse had no documented treatment costs. EPA's VSL is \$7.9 million. **CONCLUSIONS:** Based on prevalence and per occurrence health care costs, abuse and diversion pose the greatest societal burden, but these findings require verification due in part to design differences across studies and differences among populations investigated.

PODIUM SESSION I:

IMPORTANCE OF SELECTION BIAS IN HEALTH CARE RESEARCH

SB1

COMPARISON OF MEDICAL CARE CONSUMPTION BETWEEN DULOXETINE INITIATORS AND PREGABALIN INITIATORS AMONG FIBROMYALGIA PATIENTS

Sun P¹, Peng X², Sun S³, Novick D⁴, Faries D², Andrews JS², Wohlreich M², Wu A⁵
¹Kailo Research Group, Fishers, IN, USA, ²Eli Lilly and Company, Inc., Indianapolis, IN, USA, ³Kailo Research Group, Fremont, CA, USA, ⁴Eli Lilly and Company, Inc., Windlesham, Surrey, UK, ⁵Kailo Research Group, Los Angeles, CA, USA

OBJECTIVES: To compare medical care consumption between duloxetine initiators and pregabalin initiators among fibromyalgia patients. **METHODS:** We conducted a retrospective cohort study based on a US national commercial claims database (2006-2009). Fibromyalgia patients who initiated duloxetine or pregabalin in 2008, age 18 to 64, and maintained continuous health insurance coverage one year before and one year after initiation were assigned to duloxetine or pregabalin cohorts based on their initiated agent. Patients with pill coverage of the agents over last 90 pre-initiation days, with less than 30 supply days of the agents in the follow-up year, or with a diagnosis of depression, anxiety, DPNP, epilepsy or post-herpetic neuralgia before the initiation were excluded. Fibromyalgia-related medical care consumption (inpatient, outpatient, medication utilization) was compared between the two cohorts. Bootstrapping and propensity score stratification methods were used to adjust for distribution bias as well as cross-cohort differences in demographics, pre-index clinical and economic characteristics, and medication history. **RESULTS:** Compared to pregabalin initiators (n=4,838), duloxetine initiators (n = 3033) had a similar mean initiation age (49 years), female percentage (89%), percentages of patients using inpatient care (11.6% vs. 11.4%), outpatient care (100%) and medications (92.7% vs. 92.8%) in the pre-initiation year. During the post-initiation year, duloxetine initiators had fewer patients using fibromyalgia-related inpatient care (2.1% vs. 3.0%, p<0.05), fibromyalgia-related outpatient care (54.0% vs. 64.3%, p<0.05), specialty outpatient care (83.7% vs. 89.4%, p<0.05), opioids (73.5% vs. 77.1%, p<0.05), and non-steroidal anti-inflammatory drugs (38.8% vs. 41.1%, p<0.05) than pregabalin initiators did. They also had fewer inpatient admissions (0.2 vs. 0.3, p<0.05), fibromyalgia-related outpatient claims (4.7 vs. 8.3, p<0.05), specialty outpatient claims (26.1 vs. 30.4, p<0.05), and opioid claims (6.0 vs. 7.4, p<0.05). **CONCLUSIONS:** Among fibromyalgia patients, duloxetine initiators

consumed less fibromyalgia-related inpatient, outpatient, and specialty outpatient care, and had fewer post-initiation claims for opioids.

SB2

COMPARATIVE EFFECTIVENESS OF ON-PUMP AND OFF-PUMP CORONARY ARTERY BYPASS GRAFTING AMONG ELDERLY PATIENTS – A RETROSPECTIVE ANALYSIS OF MEDICARE CLAIMS DATA

Datar M, Yang Y, Mahabaleshwar R, Bentley JP, Banahan BF
University of Mississippi, University, MS, USA

OBJECTIVES: Conventional (on-pump) coronary artery bypass grafting (CABG) is a surgical procedure used to restore blood flow to the cardiac muscle in patients with coronary artery disease. Recently, some have suggested that an off-pump CABG procedure has lesser post-operative morbidity and mortality. Few studies to corroborate this finding have been conducted in the elderly population. The purpose of this study was to compare outcomes associated with on-pump and off-pump CABG among Medicare beneficiaries. **METHODS:** A retrospective cohort study design was used to analyze the 5% national sample of Medicare claims data. Elderly patients (≥ 65 years) who underwent CABG from July 1, 2006 to June 30, 2008 were identified using ICD-9-CM codes. Outcomes were assessed (using ICD-9-CM codes) following CABG surgery to December 31, 2008. Outcomes included acute myocardial infarction (AMI), revascularization such as percutaneous coronary intervention (PCI), stroke, in-hospital and all-cause mortality. Propensity scores were calculated to predict the likelihood of each individual receiving on-pump versus off-pump CABG surgery based on patient demographics and comorbidities (identified from January 1 to June 30, 2006) which were then used to match (1:1) patients in the two groups. Conditional logistic regression was used to compare the outcomes associated with the two procedures. **RESULTS:** 2,760 patients (1,380 in each group) met the inclusion criteria. Patients who underwent on-pump CABG had lower odds of in-hospital mortality (OR: 0.57; 95% CI: 0.39 – 0.83) and all-cause mortality (OR: 0.69; 95% CI: 0.56 – 0.85) as compared to off-pump CABG patients. The procedures were found to be comparable in terms of clinical outcomes including AMI, PCI and stroke. **CONCLUSIONS:** This study found that in-hospital and all-cause mortality associated with on-pump CABG was lower than off-pump CABG. Further clinical trials need to be conducted to compare the safety of on-pump versus off-pump CABG among elderly patients.

SB3

INCREMENTAL CLINICAL AND ECONOMIC BURDEN OF UNCONTROLLED PARTIAL-ONSET SEIZURES IN A PRIVATELY-INSURED POPULATION

Paradis PE¹, Parisé H¹, Duh MS², Bowers BW³, Fought E⁴
¹Groupe d'analyse, Ltée, Montréal, QC, Canada, ²Analysis Group, Inc., Boston, MA, USA, ³GlaxoSmithKline, Research Triangle Park, NC, USA, ⁴Emory University, Atlanta, GA, USA

OBJECTIVES: To assess clinical and economic consequences attributable to loss of seizure control in privately-insured patients with partial-onset seizures (POS). **METHODS:** Health insurance claims from 58 self-insured US companies between 1999 and 2009 were analyzed. Adult patients with POS (ICD-9: 345.4x, 345.5x, or 345.7x) receiving antiepileptic drugs (AED) were selected. A retrospective matched-cohort design was used to classify patients into cohorts of "uncontrolled POS" (≥ 2 AED therapy changes, followed by ≥ 1 epilepsy-related inpatient/ER visit within 1 year; and ≥ 1 diagnosis of POS) and "well-controlled POS" (no AED change and no epilepsy-related inpatient/ER visit). Patients in the well-controlled POS group were matched 1:1 with uncontrolled POS patients via propensity score matching. Matched cohorts were compared for healthcare resource use, morbidity, and costs. Statistical differences between cohorts were assessed using multivariate regressions, adjusted for demographics, baseline AED use, comorbidities and costs. **RESULTS:** From 14,377 eligible patients, 279 with uncontrolled POS (mean age=53.4, 55.6% female) were identified and matched 1:1 with well-controlled POS patients. Compared to the well-controlled POS group, the uncontrolled POS cohort had significantly more hospitalizations (adjusted rate ratio [ARR] (95% confidence interval [CI])=7.01 [5.97-8.82]), longer hospital stays (ARR (95% CI)=10.43 [9.69-11.23]), more ER visits (ARR (95% CI)=4.99 [4.25-5.87]), and more frequent outpatient visits (ARR (95% CI)=1.58 [1.55-1.62]). Fractures occurred three times more often in the uncontrolled POS group (ARR (95% CI)=3.43 [2.77-4.23]), while head injuries were twice as frequent (ARR (95% CI)=2.28 [2.02-2.56]). The uncontrolled POS group incurred nearly \$15,000 increase in direct healthcare costs (adjusted cost difference (95% CI)=\$14,966 [\$11,695-\$18,944]) versus the well-controlled group. Higher direct costs for the uncontrolled POS group were observed consistently across prescription drug and medical service categories. **CONCLUSIONS:** Uncontrolled POS was associated with significantly higher rates of healthcare resource utilization, more frequent occurrence of fractures and head injuries, and increased direct health care costs.

SB4

PROPSENSITY-SCORE MATCHING (PSM) TO CONTROL FOR SELECTION BIAS IN "REAL-WORLD" TREATMENT COMPARISONS: A CAUTIONARY TALE CONCERNING ANTIBIOTIC THERAPY FOR INFECTIOUS DISEASE

Berger A¹, McKinnon PS², Larson K², Crompton M², Hennegan K¹, Weber DJ³, Boening AJ², Oster G¹

¹Policy Analysis Inc. (PAI), Brookline, MA, USA, ²Cubist Pharmaceuticals, Inc., Lexington, MA, USA, ³University of North Carolina School of Medicine, Chapel Hill, NC, USA

OBJECTIVES: In infectious disease, treatment decisions are often influenced by concerns about antibiotic resistance, which often leads to restriction of newer agents to sicker patients (i.e., selection bias). PSM is often used to control for this problem in "real-world" comparisons. We examined the adequacy of PSM in a "real-world" comparison of vancomycin versus daptomycin as treatment for complicated skin and skin structure infections (cSSSI). **METHODS:** Using a database